



[BILLING CODE 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-day Comment Request:

The Framingham Heart Study (FHS)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the Federal Register on May 7, 2013, pages 26639-41 and allowed 60-days for public comment. No public comments were received. The National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

DIRECT COMMENTS TO OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, OIRA_submission@omb.eop.gov or by fax to 202-395-

6974, Attention: NIH Desk Officer.

COMMENT DUE DATE: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

FOR FURTHER INFORMATION: To request more information on the proposed project or to obtain a copy of data collection plans and instruments, contact Dr. Gina Wei, Division of Cardiovascular Sciences, NHLBI, NIH, Two Rockledge Center, 6701 Rockledge Drive, MSC 7936, Bethesda, MD, 20892-7936, or call non-toll-free number (301) 435-0416, or e-mail your request, including your address to: weig@nhlbi.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

PROPOSED COLLECTION: The Framingham Heart Study, 0925-0216, Revision National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH).

Need and Use of Information Collection: The Framingham Heart Study will continue to conduct morbidity and mortality follow-up, as well as examinations, for the purpose of studying the determinants of cardiovascular disease. Morbidity and mortality follow-up will continue to occur in all of the cohorts (Original, Offspring, Third Generation, Omni Group 1, and Omni Group 2). Examinations will continue to be conducted on the Original, Offspring, and Omni Group 1 Cohorts. The numbers of Offspring and Omni Group 1 participants to be examined for this OMB submission are much smaller than those during the last OMB approval period. This is because a great

majority of these two cohorts have already completed their examinations. The small number of participants remaining to be examined is reflected in the decrease in the estimated annualized burden hours for these two cohorts as well as for the entire study, compared to the last OMB approval period.

OMB approval is requested for 3 years. There is no cost to the respondents other than their time. The total estimated annualized burden hours are 4264.

Estimated Annualized Burden Hours, Original Cohort

Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Time per Response (in hours)	Total Annual Burden Hour
I. PARTICIPANT COMPONENTS				
A. PRE-EXAM				
a. Telephone contact to set up appointment	60	1	10/60	10
b. Exam Appointment, Scheduling, Reminder, and Instructions	55	1	35/60	32
B. EXAM – Cycle 32				
a. Clinic exam	25	1	45/60	19
b. Home or nursing home visit	25	1	65/60	27
C. ANNUAL FOLLOW-UP				
a. Records Request	60	1	15/60	15
b. Health Status Update	45	1	15/60	11
SUB-TOTAL:PARTICIPANT COMPONENTS	60*	-----	-----	114
II. NON- PARTICIPANT COMPONENTS				
A. Informant Contact (Pre-exam and Annual Follow-up)	25	1	10/60	4
B. Records Request (Annual follow-up)	50	1	15/60	13
SUB-TOTAL:NON-PARTICIPANT COMPONENTS	75	-----	-----	17

* Number of participants as reflected in Rows I.A.a and I.C.a. above

Estimated Annualized Burden Hours, Offspring Cohort and Omni Group 1 Cohort

Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Time per Response (in hours)	Total Annual Burden Hour
I. PARTICIPANT COMPONENTS				
A. PRE-EXAM				
a. Telephone contact to set up apt or Health status update	300	1	10/60	50
b. Appt. or update Confirmation	250	1	10/60	42
c. Food Frequency Form	250	1	10/60	42
B. EXAM				
a. Clinic Exam	100	1	175/60	292
b. Home or nursing home visit	100	1	60/60	100
c. Consent Forms	200	1	20/60	67
C. ANNUAL FOLLOW-UP				
a. Records Request	2292	1	15/60	573
b. Health Status Update	1833	1	15/60	458
SUB-TOTAL: PARTICIPANT COMPONENTS	2292*	-----	-----	1624
II. NON- PARTICIPANT COMPONENTS				
A. Informant contact (Pre-exam and Annual Follow-up)	229	1	10/60	38
B. Records Request (Annual follow-up)	2292	1	15/60	573
SUB-TOTAL:NON-PARTICIPANT COMPONENTS	2521	-----	-----	611

* Number of participants as reflected in Rows I.C.a. above

Estimated Annualized Burden Hours, Generation 3 Cohort and Omni Group 2 Cohort

Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Time per Response (in hours)	Total Annual Burden Hour
I. PARTICIPANT COMPONENTS – ANNUAL FOLLOW-UP				
A. Records Request	3212	1	15/60	803
B. Health Status Update	3212	1	15/60	803
SUB-TOTAL: PARTICIPANT COMPONENTS	3212*	-----	-----	1606
II. NON- PARTICIPANT COMPONENTS – ANNUAL FOLLOW-UP				
A. Informant contacts	160	1	10/60	27
B. Records Request	1060	1	15/60	265
SUB-TOTAL:NON-PARTICIPANT COMPONENTS	1220	-----	-----	292

* Number of participants as reflected in Rows I.A. and I.B. above

Summary of 3 Tables Combined -Total Estimated Annualized Burden Hours

Type of Respondent	Number of Respondents	Number of Responses Per Respondent	Average Time per Response (in hours)	Total Annual Burden Hour
Participants	5564	1	36/60	3344
Non-Participants	3816	1	14.5/60	920
Totals	9380			4264

(Note: reported and calculated numbers differ slightly due to rounding.)

Lynn Susulske

NHLBI Project Clearance Liaison

National Institutes of Health

Michael Lauer,

Director, DCVS

National Institutes of Health

[FR Doc. 2013-23060 Filed 09/20/2013 at 8:45 am; Publication Date: 09/23/2013]